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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/754,115

01/07/2004

Timothy D. Hey

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EXAMINER

KOSSON, ROSANNE

ART UNIT

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1652

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/754,115	<b>Applicant(s)</b> HEY ET AL.	
	<b>Examiner</b> Rosanne Kosson	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-25,34-37,40,41 and 43-51 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-25,34-37,40,41 and 43-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 21-25,34-37,40,41 and 43, 46, 50 and 51 each claim in part.

## **DETAILED ACTION**

### ***Election/Restrictions***

The amendment filed on March 14, 2008 has been received and entered. Claims 21, 24 and 36 have been amended. Claim 21 has been broadened to recite that each of the proteins in the complex has at least 95% sequence identity to the respective protein in the elected invention. Claim 36 has been broadened to delete the limitations that the different proteins recited in the claim are variants in which the differences between the variant proteins and the proteins used in the method of the elected invention are conservative amino acid substitutions. Claims 38, 39 and 42 have been canceled. Claims 43-51 have been added. Once again, the restriction requirement and Applicants' subsequent presentation of claims to non-elected inventions have been discussed at length in the previous Office actions and elsewhere with Applicants. The instant claims, to the extent that they recite variants of non-elected B and C proteins, i.e., proteins having 95% or 99% sequence identity to SEQ ID NOS:22, 56, 25 and 57, still recite non-elected inventions. The claims reciting these variant proteins, therefore, remain withdrawn from prosecution as being drawn to non-elected inventions. Accordingly, claims 21-25, 34-37, 40, 41 and 43-51, to the extent that they read on the elected invention, a method of inhibiting an insect, comprising contacting the insect with a complex comprising SEQ ID NO:34 as the A protein, SEQ ID NO:45, 22 or 56, excluding variants of SEQ ID NOS:22 and 56, as the B protein and SEQ ID NOS:47, 25 and 57, excluding variants of SEQ ID NOS:25 and 57, as the C protein are examined on the merits herewith. This point was discussed in detail in the previous Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

In view of Applicants' amendments to the claims, because the transitional phrase "consisting essentially of" has been deleted, the enablement rejection with respect to this term is withdrawn as being no longer pertinent.

Claims 21-25, 36, 37 and 41 are again rejected, and claims 43, 47, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising SEQ ID NO: 34, plus one of SEQ ID NOS:22, 45 or 56, plus one of SEQ ID NOS:25, 47 or 57, does not reasonably provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising any variant having at least 95% sequence identity to any or all of the aforementioned proteins. Regarding claim 36, now split into claims 36 and 50, the specification, while being enabling for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising SEQ ID NO: 34, plus one of SEQ ID NOS:25, 47 or 57, does not reasonably provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising any variant of any or all of these proteins in which one or all of the amino acids is replaced with a conservative substitution. Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection has been discussed at length in the previous Office actions.

Also, as previously discussed, Applicants highlighted during their in-person interview on June 7, 2007 that their results are surprising results because there is no correlation between structure and function for the various *Xenorhabdus* and *Photorhabdus* proteins disclosed in the specification. As a result, the function of their complex of SEQ ID NO:34, SEQ ID NO:45 and

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SEQ ID NO:47, the elected proteins A, B and C (the elected invention) could not have been predicted. As further previously discussed, Applicants have claimed several very large genera of proteins, but have not disclosed any species of these genera (functional variants of the named proteins). Because Applicants have not disclosed any species of these claimed genera, and because Applicants have not provided any systematic procedure for identifying these undisclosed species, it cannot be predicted that such species exist. Additionally, it would be undue experimentation to come up with the systematic guidance needed to identify and test these species, and the amount of random make-and-test-for-function experimentation that would be required to practice the full scope of the claims is undue. Despite the enablement rejection, however, Applicants have broadened their claims, as noted above.

In their response, Applicants assert that they are entitled to claims reciting 95% sequence identity to the elected A, B and C sequences (SEQ ID NOS:34, 45 and 47), because the same techniques are used to screen all the variants, whether they have 95% or 99% sequence identity to the elected sequences. Applicants cite Example 14 of the Written Description Guidelines to support their position. Applicants have not addressed the rejection of claim 36 and its dependent claims in the previous Office action.

In reply, the rejection is not that different techniques are required to screen polypeptides that differ by 5% relative to a particular polypeptide sequence vs. polypeptides that differ by 1%. The rejection is that the claims recite an enormous number of variants of the elected sequences and that one of skill in the art would have to screen  $5.5 \times 10^{22}$  clones of mutants to identify one clone that produces an active A protein (a protein having the stand-alone insecticidal activity of SEQ ID NO:34),  $1.5 \times 10^{13}$  clones of mutants to identify one clone that produces an active B protein (a protein having the insecticidal enhancing activity of SEQ ID NO:45) and  $4.6 \times 10^8$  clones of mutants identify one clone that produces an active C protein (a protein having the

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insecticidal enhancing activity of SEQ ID NO:47). This physically impossible amount of required random screening is undue, particularly in view of both the lack of correlation between structure and function for the elected polypeptide sequences and the lack of disclosure of any species of the claimed genera, apart from the elected sequences.

As for the Written Description Guidelines, this is an enablement rejection, not a written description rejection. Example 14 does not correspond to Applicants' fact pattern, because, in the Example, the claim is limited to polypeptide sequences that retain all the amino acids required for function and 95% of the total amino acids, and it is considered that such undisclosed species would describe adequately the structure of the polypeptides in the genus. This example is not a determination of enablement, which is very fact specific. In the Example, the specification did not disclose that SEQ ID NO:3 provided unexpected results due a lack of correlation between structure and function among polypeptides from different species of organisms, sequences that differ greatly on the amino acid level but have the same function and sequences that vary very little on the amino acid level yet do not retain function. Moreover, the length of SEQ ID NO:3 is not indicated. Thus, the reader would not know how many clones would have to be screened to identify one positive clone, as an indication of whether or not the claim to the variants is enabled.

Regarding claims 36 and 50, Applicants have not explained how the claimed method of using the variant proteins having unlimited "conservative" amino acid substitutions is enabled by their specification that does not disclose any such variants or provide any evidence that such variants could be used in the claimed method. This aspect of the rejection was not addressed.

In view of the foregoing, the rejection of record is maintained.

***Double Patenting- Obviousness-Type***

Claims 21-25, 34-37, 40 and 41 are again provisionally rejected, and claims 43-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 29 and 33 of copending Application No. 11/070,573. This rejection has been discussed in the previous Office actions.

Applicants have declined to respond to this rejection, but a response is due and may not be deferred. Applicants note that they have responded to a restriction requirement in the copending application, but Applicants' response is the election of an invention. Applicants have not canceled any claims drawn to polypeptides or methods of using polypeptides. In particular, Applicants have not canceled any claims to the conflicting subject matter.

In view of the foregoing, the rejection of record is still outstanding and is maintained.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner



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should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652  
rk/2008-04-18

/Rebecca E. Prouty/  
Primary Examiner,  
Art Unit 1652